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No. 92-173

# In the Supreme Court of the United States

OCTOBER TERM, 1992

EFAMOL, LTD., PETITIONER

*v.*

UNITED STATES OF AMERICA

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT*

## BRIEF FOR THE UNITED STATES IN OPPOSITION

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## QUESTION PRESENTED

1. Whether petitioner failed to establish a genuine issue of material fact as to whether evening primrose oil is generally recognized as safe when used as a component of food.

2. Whether petitioner failed to establish a genuine issue of material fact as to whether barrels of evening primrose oil labeled "pure vegetable oil" were misbranded.

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## BRIEF FOR THE UNITED STATES IN OPPOSITION

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### OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A1-A10) is reported at 961 F.2d 808. The opinion of the district court (Pet. App. A13-A16) is unreported.

### JURISDICTION

The judgment of the court of appeals was entered on April 7, 1992. A petition for rehearing was denied on June 12, 1992. Pet. App. A11. The petition for a writ of certiorari was filed on July 28, 1992. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

## STATEMENT

1. Petitioner, a British company, exports evening primrose oil (EPO) obtained from the crushed seeds of the evening primrose plant for use in dietary supplements. Pet. App. A3. In 1979, the Food and Drug Administration (FDA) informed petitioner that it did not view EPO as "generally recognized as safe" (GRAS) for use in dietary supplements. *Ibid.* A substance that is intended to be used as a component of food, and that is not GRAS, is deemed a "food additive" under 21 U.S.C. 321(s).[1] A food additive can be marketed in interstate commerce only if the FDA approves a petition containing scientific data submitted pursuant to 21 U.S.C. 348. Petitioner has submitted no such petition to the FDA. Pet. App. A3 n.1. Instead, petitioner informed the FDA that it would cease exporting EPO to the United States. *Id.* at A3.

Despite petitioner's assurances that it would cease exporting EPO, petitioner shipped EPO in bulk to a California company that mixes the EPO with Vitamin E, puts the mixture into gelatin capsules, and markets the capsules as a dietary supplement. In 1989, the United States, pursuant to a district court order, seized 45 barrels of EPO labeled "PURE VEGETABLE OIL." Pet. App. A3-A4.

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[1] Section 321(s) provides, in part:

> The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food * * *, if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures * * * to be safe under the conditions of its intended use * * *.

2. The district court granted the government's motion for summary judgment. Pet. App. A13-A16. First, the court held that the seized barrels of EPO were misbranded within the meaning of 21 U.S.C. 343. The district court found that the EPO was labeled as "PURE VEGETABLE OIL," which consumers would interpret as meaning a cooking or salad oil, while EPO is commonly referred to only as evening primrose oil. In addition, the court found that petitioner did not qualify for a limited regulatory exemption for misbranded articles because there was no written agreement between petitioner and the California company providing that the oil would be properly labeled when further processed for public sale. Pet. App. A14-A15.

The court also held that EPO is an unsafe food additive under 21 U.S.C. 321(s) and 348(a). The court concluded that EPO is not generally recognized as safe because several qualified experts whose opinions the government submitted with its motion for summary judgment concluded that EPO is not GRAS. Pet. App. A15. The court thus held that the seized EPO is subject to condemnation and destruction. *Id.* at A16.

3. The court of appeals affirmed. Pet. App. A1-A9. The court first addressed the misbranding issue, concluding that petitioner had not raised any genuine issue of material fact, either on the question whether the label "PURE VEGETABLE OIL" is misleading to consumers or whether petitioner had shown the existence of a written agreement with the California company to properly label the product when it is repackaged. *Id.* at A4-A7.

The court then turned to the question whether EPO is GRAS. It explained that petitioner was required to produce scientific studies showing that

EPO is safe when used as a component of a dietary supplement, and that these studies must be "generally available to the community of experts and subjected to peer evaluation, criticism and review appropriate to establish such safety." Pet. App. A8, citing 21 C.F.R. 170.30(b), and *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 652 (1973). Petitioner's evidence, the court concluded, "fails to meet the above criteria" because some of the data concerned "EPO's use as a drug and not as a dietary supplement," while "[o]ther data w[ere] based on unpublished materials, which were not subjected to peer evaluation. * * * In comparison, the government's witnesses testified that there is insufficient published scientific literature showing that EPO is safe and there is insufficient animal or human testing of EPO's use as a dietary supplement." Pet. App. A8-A9. The court therefore concluded that summary judgment for the government was appropriate. Pet. App. A9.

## ARGUMENT

Petitioner urges the Court to grant review to decide three questions. The first two questions are not properly presented by this case, and the third is entirely fact-bound. Accordingly, further review is not warranted.

1. Petitioner contends (Pet. 14-25) that the Court should grant review in this case to decide whether expert testimony under Rules 702 and 703 of the Federal Rules of Evidence must be based on theories or discoveries that are "sufficiently established to have gained general acceptance in the particular field in which [the theory or discovery] belongs." *Frye* v. *United States*, 293 F. 1013, 1014 (D.C. Cir. 1923). As we explain in our brief in opposition in *Jakobetz* v.

*United States*, No. 91-7921, the courts of appeals are divided on that issue. Compare *Christophersen* v. *Allied-Signal Corp.*, 939 F.2d 1106, 1111 (5th Cir. 1991) (en banc) (expert testimony based on novel scientific theories or discoveries is admissible only if the theory or discovery is "sufficiently established to have gained general acceptance in the particular field in which it belongs"), cert. denied, 112 S. Ct. 1280 (1992), with *United States* v. *Piccinonna*, 885 F.2d 1529, 1536 (11th Cir. 1989) (admissibility of novel scientific evidence under Federal Rules of Evidence should turn on its relevance and materiality, and whether it will assist the jury). Contrary to petitioner's contention, however, that issue is not presented in this case.

The Federal Food, Drug, and Cosmetic Act expressly requires proof that a food additive is "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures * * * to be safe under the conditions of its intended use." 21 U.S.C. 321(s). The Act thus settles the dispute over whether a novel scientific theory or technique must have "gained general acceptance" in the context of litigation over components of food by requiring that the safety of the substance must be "generally recognized" by experts. An FDA regulation reinforces that requirement by providing that the safety of the substance must be "common knowledge" in the relevant scientific community and that opinions must "ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information." 21 C.F.R. 170.30.

The court of appeals reasonably concluded that petitioner's evidence did not meet the rigorous scien-

tific standard established by the Act and its regulations.[2] The court explained that petitioner's experts relied on unpublished materials that had not been subjected to peer review, as well as on studies of EPO's use as a drug rather than a component of food. Pet. App. A8. The court also stated, in a footnote, that "the additional data relied on by [petitioner] is insufficient under Rule 703." Pet. App. A9 n.4. Although Rule 703, as interpreted by the court, supports the court's conclusion, application of that Rule was not necessary to the court's decision. Because petitioner failed to submit evidence sufficient to show that EPO is "generally recognized, among experts * * * [,] to be safe," 21 U.S.C. 321(s), this case is not an appropriate vehicle for resolving the general question whether expert testimony admitted under Fed. R. Evid. 702 and 703 must be based on information that is "sufficiently established to have gained general acceptance in the particular field in which it belongs." *Frye* v. *United States*, 293 F. at 1014.

2. Petitioner contends (Pet. 25-29) that the court of appeals erred in stating that petitioner bore the burden of proving that EPO is generally recognized as safe. That issue also is not properly presented in this case. Although the court of appeals referred without discussion to petitioner's burden of proof (Pet. App. A4, A7, A9), its decision rests on well settled summary judgment principles.

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[2] That standard has been recognized in decisions of this Court and other courts. See, *e.g.*, *United States* v. *Rutherford*, 442 U.S. 544, 549 n.7 (1979); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 629, 632 (1973); *United States* v. *225 Cartons, More or Less, of an Article or Drug*, 871 F.2d 409, 413 (3d Cir. 1989); *United States* v. *Articles of Drug Consisting of the Following: 5,906 Boxes*, 745 F.2d 105, 117 (1st Cir. 1984).

The district court concluded that the government had presented sufficient evidence to establish that EPO is not GRAS. See Pet. App. A15. The court of appeals discussed petitioner's contrary evidence at length and concluded that it "fails to meet the * * * criteria" for expert evidence established by the Act. *Id.* at A8. The court of appeals compared petitioner's inadequate factual showing to the government's showing, which was based on the opinions of experts that EPO has not been shown to be safe. *Id.* at A8-A9. In these circumstances, established principles of summary judgment required the court of appeals to affirm the judgment for the government.

In *Anderson* v. *Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986), the Court explained that the non-moving party can defeat a motion for summary judgment only by raising a genuine issue of material fact, which requires a finding that "there is sufficient evidence favoring the nonmoving party" to allow the factfinder to find in favor of the non-moving party. "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-250 (citations omitted). Under *Anderson*, "[t]he movant has the burden of showing that there is no genuine issue of fact, but the [non-moving party] is not thereby relieved of [i]ts own burden of producing in turn evidence that would support a jury verdict." 477 U.S. at 256. Here, the government met its burden under Fed. R. Civ. P. 56 by presenting sufficient evidence to allow a finder of fact to rule in its favor. Because petitioner failed to produce evidence to create a genuine issue of material fact, the government was entitled to summary judgment. See *United States* v. *Articles of Food & Drug Consisting of Coli-Trol 80*, 518 F.2d 743, 747 (5th Cir. 1975) (government is entitled to prevail in a GRAS case when it presents

an adequate case and the company responds with irrelevant or insufficient evidence).

In *Celotex Corp.* v. *Catrett*, 477 U.S. 317 (1986), the Court explained that the moving party is entitled to summary judgment if the opposing party "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." 477 U.S. at 322. Although the court of appeals twice referred to *Celotex* (see Pet. App. A4, A9), the *Celotex* principle does not apply in this case. In this case, unlike in *Celotex*, the government made an adequate factual showing to support a judgment in its favor, and petitioner failed to raise a genuine issue of material fact. Consequently, the government was entitled to summary judgment. The court's passing references to the burden of proof in GRAS cases, like its reference to Rule 703, did not affect its decision. This case therefore does not present an occasion for the Court to decide the proper allocation of the burden of proof in GRAS cases.[3]

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[3] In any event, petitioner's own description of the cases that it cites demonstrates that any nascent disagreement in the lower courts on this issue is not ripe for review by this Court. Petitioner states that some courts of appeals, "[w]ithout much discussion," have placed the burden on the FDA. Pet. 28, citing *United States* v. *An Article of Food Consisting of 345/50-Pound Bags*, 622 F.2d 768, 771 (5th Cir. 1980); *United States* v. *Ewig Bros. Co.*, 502 F.2d 715, 719 (7th Cir. 1974), cert. denied, 420 U.S. 945 (1975). Although petitioner states that "[o]ther courts of appeals appear to place the burden on the manufacturer," it concedes that those courts did not "focus[] on the burden of proof issue because it was not central to the decision." Pet. 28-29 & n.37, citing *United States* v. *An Article of Food*, 752 F.2d 11, 15 (1st Cir. 1985); *United States* v. *An Article of Food*, 678 F.2d 735, 739 (7th Cir. 1982).

3. Finally, petitioner contends (Pet. 29-30) that the determination of the court of appeals and the district court that the EPO was misbranded "is based on a misreading of Dr. Ross' testimony" and certain documents submitted by petitioner. Pet. 29. The court of appeals concluded (Pet. App. A5-A6) that (1) Dr. Ross's testimony was relevant only to EPO in gelatin capsules, not to EPO in bulk form, and (2) "a simple reading" of the collection of letters and facsimile transmissions proffered by petitioner demonstrates that the EPO was not exempt from the labeling requirements. As petitioner itself acknowledges (*id.* at 30), those fact-bound determinations are of no general significance. No further review is warranted.[4]

[4] The lower courts' ruling that the barrels of EPO were misbranded provides an independent basis for the judgment of forfeiture. Consequently, further review of the first two questions presented in the petition—which are relevant to the court of appeals' alternative holding that the barrels of EPO are subject to forfeiture because EPO is not GRAS—is not warranted for the additional reason that resolution of those questions in petitioner's favor would be very unlikely to affect the outcome of this case. Petitioner suggests (Pet. 30) that it could avoid the forfeiture by relabeling the EPO under 21 U.S.C. 334(d). But that possibility is quite remote. Petitioner could avoid a forfeiture under Section 334(d) only if (1) it ultimately prevailed on the GRAS issue, and (2) the court exercised its discretion to permit petitioner to relabel the EPO. In deciding whether to permit relabeling, the court would consider a variety of factors, including whether the petitioner deliberately mislabeled the EPO to avoid detection by the Customs Service in light of the FDA's Import Alert for EPO (see Pet. App. A3 n.1), and whether EPO seized almost four years ago is still fresh enough to market.

## CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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